# Q4 FY20 Registration Review FRNs

FRN #1, FRL TBD (Not submitted yet): Contains all orange and black text chemicals (except for commodity fumigants and zinc phosphide) in Draft Risk Assessments table. Timing: mid-October
FRN #2 FRL TBD (Not submitted yet): Contains Chlorpyrifos DRAs. Timing: mid- October
FRN #3 FRL TBD (Not submitted yet): Contains Zinc Phosphide DRAs. Timing: mid- October
FRN #4 FRL TBD (Not submitted yet): Contains Commodity Fumigant DRAs. Timing: mid-October
FRN #5 FRL TBD (Not submitted yet): Contains Sulfuryl Fluoride Residential Post-Clearance Assessment (and EFED DWA/DRA). Timing: September

| **Draft Risk Assessments** (Red = AA briefing & fact sheet, Orange = Program review & fact sheet, Black = Summary) | |
|---|---|
| Antimicrobials: | Benzoic Acid, Ethylene Oxide (Propose to move to FY21 Q1), Dimethoxane, Organic Esters of Phosphoric Acid (OEPA)*, Polymeric Betaine |
| Conventionals: | 4-Aminopyridine (4-AP), Acrolein, Benzyl benzoate* (HH only), Butoxypolypropylene glycol (BPG)*, Chlorpyrifos, Commodity Fumigants* (Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO) & Inorganic Sulfites, Cycloate, Difenoconazole, Fenbuconazole, Ferbam, HPPD Inhibitors (Isoxaflutole, Mesotrione, Tembotrione, Topramezone, & Pyrasulfotole), Phorate (OP, eco only), Phosmet (OP, eco only), Sulfuryl Fluoride**, Thiram, Tolfenpyrad***, Zinc Phosphide, Ziram |
| Biopesticides: | N/A |

* DRA and PID both are anticipated to publish in Q4; summaries appear in the PID section of this document
** Residential Post-Clearance Assessment and EFED DWA/DRA Only
*** Registration Review Round 2

# Q4 Draft Risk Assessments

## Q4 Conventional DRA Fact Sheets

### 4-Aminopyridine (4-AP) DRA

**Current Status**

- Avicide that acts as a neurotoxin; member of the pyridine family
- Restricted use pesticide (RUP) that must be applied by certified applicators or those under their direct supervision
- Five end-use products are registered as bird control agents (treated bait) for nuisance birds
- Bait consists of coarse mixed grains, whole kernel corn, or pelleted corn
- Application sites are on or in bird feeding, nesting, and roosting sites across urban, rural, agricultural, and non-agricultural locations

**Key Points**

- PRD negotiated with the 4-AP registrants to make changes to their labels to minimize potential environmental exposures and associated eco risks that could result from rainfall interaction
- Improved label language will allow waiver of the data requirements listed in the GDCI
- Similarly, drinking water assessment for human health was not conducted due to limited environmental exposures

**Human Health Risk Assessment Conclusions**

- No dietary exposure from food or water is expected based on the use patterns
- Residential applicator exposure is not expected since 4-aminopyridine can only be applied by certified applicators
- The occupational applicator combined MOE is 240 (LOC = 30) and is not of concern

**Ecological Risk Assessment Conclusions**

- Potential risk concerns for birds and mammals on an acute basis (chronic risk uncertain)
- Low potential risk for fish, aquatic invertebrates, and aquatic and terrestrial plants
- Risk to terrestrial invertebrates not expected due to limited exposure pathway from limited application methods (bait by tray)

**Communications**—No additional communications are planned. This chemical has attracted attention over the potential risk to non-target species, particularly those protected by the Migratory Bird Treaty Act.

# Acrolein DRA

**Current Status**

- Acrolein has dual uses with microbiocide uses being managed by AD and aquatic herbicide uses being handled by PRD.
- Acrolein is a Restricted Use Pesticide with a history of fatal human health incidents
- As an antimicrobial pesticide, acrolein is used in oilfield and gas-field water injection systems in order to control anaerobic and aerobic bacteria
- As an herbicide, acrolein is used to control weeds in flowing irrigation ditches, and certain reservoirs used for managing irrigation water.
- EFED has completed a draft of the risk assessment for review, HED's draft is currently in development, and AD's DRA is completed.
- Publication Target is September 30, 2020

**Key Points**

- Fate and ecological data required (mostly ecological effects studies) from the Registration Review DCI have not been received. Consequently, estimated risks are similar to that in Reregistration.

**Human Health Risk Conclusions**

- For acrolein's antimicrobial uses, due to the closed-loading and restricted use of these products, no human health (dietary, residential, or occupational) exposures are expected when used according to the label use directions by trained personnel or licensed applicators. Therefore, risks are not expected.
- A drinking water assessment has been completed.
- The toxicological database is being reviewed for registration review
- For the herbicidal use, there are anticipated occupational exposures to acrolein as well as dietary exposures to glycidol, a metabolite of acrolein, specifically as it relates to consumption of fish from treated waters by subsistence fisherman. Based on the use pattern, no direct residential or non-occupational exposures are anticipated for conventional uses.

**Ecological Risk Assessment Conclusions**

- For acrolein's antimicrobial uses, due to the closed-loading and restricted use of these products, environmental (terrestrial or aquatic) exposures are not expected when used according to the label use directions by trained personnel or licensed applicators. Therefore, risks are not expected.
- For the herbicide use, there is a potential for direct effects to non-listed aquatic and terrestrial animals and plants.

**Communications**—No additional communications are planned.

# Chlorpyrifos DRA

**Current Status**

- Chlorpyrifos is an organophosphate insecticide registered for a large variety of agricultural uses and non-agricultural uses.
- Residential registrations are limited to roach bait products with child resistant packaging (EPA Reg. No. 9688-67) and ant mound treatments which may only be applied by commercial applicators.
- The science divisions are drafting the risk assessments at this time.
- The PID is currently scheduled for October 2020. As such, OPP anticipates establishing the public comment for the DRAs concurrently with the PID.
- DRA Publication Target: on or before 9/21/20[1]
- On August 7, 2019, the petitioners from the 2007 petition (PANNA-NRDC), in addition to several states, petitioned the Ninth Circuit Court to review orders issued by the EPA denying the 2007 petition to ban food uses on chlorpyrifos ("LULAC 2").

**Key Points**

- The Registration Division has not approved new uses since (late) 2018.
- Significant public interest
- Oral arguments for LULAC 2 have been scheduled for July 28, 2020. Based on the timelines for other cases, the ruling could potentially be issued approximately 70 days later.
- The OP SAP is scheduled for September.

**Human Health Risk Conclusions**

- Dietary and residential risk assessments will be presented both with and without retention of the 10X FQPA safety factor.
    - Dietary risks of concern were identified for water only with and without retention of the 10X FQPA Safety Factor; no dietary risks of concern were identified from food only. Mitigation will be proposed to address risks of concern driven by the drinking water assessment.
    - Drinking water dietary assessment does not include non-agricultural uses, such as turf, gold course, livestock, and mosquito abatement. As it stands, non-agricultural uses would not fit into the risk cup.
    - There are no residential risks of concern.
    - For aggregate risks, the lowest/most protective DWLOC is 4 ppb (for infants) with the 10X retained and 43 ppb with the 10X removed. These values can be compared to the multiple EDWCs generated by EFED (in progress) to determine risk.
- Occupational risk assessments are conducted both with and without retention of a 10X database uncertainty factor.
    - Many occupational scenarios are of concern with the retention of a 10X $UF_{DB}$. With the 10X $UF_{DB}$ removed, there are still some scenarios of concern.
- In the updated drinking water exposure assessment, early indications are that modeled concentrations pass for the subset of uses under consideration, but there may be concerns with monitoring data concentrations, relative to the DWLOCs.

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[1] In its response to objections on the chlorpyrifos petition, EPA committed to a revised human health risk assessment by summer of 2020 and PID by October 2020.

**Ecological Risk Assessment Summaries**

- Potential risks of concern for mammals, birds, fish and terrestrial/aquatic invertebrates based on RQs.
- Citrus and tart cherries are associated with some of the highest RQs, but RQs exceed the LOC for all uses.
    - Maximum acute RQs of 4900 and chronic RQs of 8600 for terrestrial and aquatic invertebrates
- Mammals
    - Acute RQs are up to 20 with half of the uses resulting in RQs above 5.
    - Chronic RQs up to 625 (reproduction: 30% loss of pups) with 50% of uses resulting over 147
    - Chronic RQs up to1900 (growth: decreased weight), with 50% of uses with RQs over 450.
- Birds
    - Half of uses assessed resulted in acute RQs above 93 with a maximum of 390.
    - Half of uses assessed resulted in chronic RQs above 14 with a maximum of 58.
- Fish
    - Maximum acute and chronic RQs of 160 and 120, respectively
    - Half of all uses were above RQs of 32 and 20, respectively
- Terrestrial and aquatic invertebrates
    - Maximum acute RQs are 4300 and 4900, respectively, with 50% of all uses having RQs over 820 and 880, respectively.
    - Chronic aquatic RQs ranges up to 8600 with over 50% of uses assessed resulting in RQs above 1540.
    - No tier I chronic bee data available.

- Numerous incidents in all taxa, including plants, have been reported as associated with the use of chlorpyrifos.
    - Chlorpyrifos has been reported as the 'probable' or 'highly probable' causative agent for 110 adverse aquatic incidents (*e.g.*, fish kills).
    - Sixty-four (64) bird incidents have been associated with a certainty index of 'possible', 'probable' or 'highly probable'

**Communications**

- Anticipate separate rollout; OCSPP/OPA will have a desk statement on-hand for any press inquiries
- Some press for the DRAs is possible

## Commodity Fumigant DRAs - Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO)

The DRAs and PIDs for the commodity fumigants (Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO)) will be released together in Q4, however the inorganic sulfite (another commodity fumigant) DRAs were uploaded into the docket on May 4, 2020 (part of the FY2020 Q2 DRA Package). See the fact sheet for these cases under the [ HYPERLINK \l "_Commodity_Fumigants_DRAs" ] below.

# Cycloate DRA

**Current Status**

- Cycloate is a systemic, broad-spectrum, and pre-emergent herbicide registered for control of certain grasses and broadleaf weeds on three agricultural use sites: table beets, spinach, and sugar beets.
- Environmental Risk Assessment was signed July 9, 2020 and the Human Health Risk Assessment will be signed by the end of July 2020.

**Key Points**

- About 40 percent of the spinach crop is treated with cycloate, suggesting that this herbicide is important in U.S. spinach production. No usage data on table beet, but while annual acres grown were only about 15,000 in the last Census of Agriculture, cycloate use could be similarly important. Sugar beet usage is very low.
- 92 percent of average yearly (reported) usage of cycloate was in California spinach.
- The average annual use dropped drastically from 2001-2005 average (237,000 lbs/yr) to 2008-2012 average (45,000 lbs/yr) entirely due to usage in sugarbeet. Data from 2018 indicate that use on sugarbeet continues to be insignificant.
- The development of genetically modified sugarbeet varieties with resistance to gylphosate may have contributed to the reduction of cycloate usage on sugarbeet production.

**Human Health Risk Assessment Conclusions**

- In 2014, a 10X $UF_{DB}$ was added to both acute and chronic dietary exposures for lack of a DNT. Request to waive that DNT was recently denied. The agency will also apply a 10x to dermal occupational scenarios.
- The acute PAD has been refined (from 20 mkd to 27 mkd) by using benchmark dose analysis, resulting in an update to both the POD and safety factors. There are no acute dietary risks of concern. However, chronic dietary exposures were above the level of concern, 270% of the cPAD for all infants and 100% of the cPAD for the general population. Major contributor is drinking water.
- There are risks of concern for occupational handler scenarios (dermal and inhalation), as well as occupational applicator scenarios (inhalation). Risks for some, but not all, scenarios are mitigated with PPE.
- There are no residential exposures, so aggregate risks are equivalent to the dietary (food + drinking water) analyses.
- Non-occupational spray drift was not conducted.

**Ecological Risk Assessment Conclusions**

- The ecological DRA identified risks to mammals, terrestrial invertebrates, aquatic plants, and potentially terrestrial plants based on registered uses.
- For all uses (garden beets, sugar beets, and spinach), potential risk was similar for all application types (broadcast/band application with mechanical or irrigation incorporation treatment, and soil injection and/or combined with fertilizer).
- Mortality in the chronic adult honey bee toxicity study results in the potential for risk to bees on treated fields for garden and sugar beet crops grown for seed. No colony-level effects data are available for honey bees, but PRD will work with EFED to determine if additional data are needed.

**Communications**

- In addition to posting in the FR for public comment, the agency plans to develop a desk statement due to the DNT requirements.

# HPPD Inhibitor DRAs - Isoxaflutole, Mesotrione, Tembotrione, Topramezone, & Pyrasulfotole

**Background**

- The HPPD inhibitors are systemic herbicides that inhibit the enzyme p-hydroxyphenyl pyruvate dioxygenase (HPPD). HPPD inhibition disrupts carotenoid biosynthesis, which leads to the destruction of chlorophyll and eventually to plant death.
- The HPPD inhibitors are used in agricultural, non-agricultural, and residential settings for control of broadleaf and grass weeds.

**Human health risks:**

- There are no non-cancer human health risks of concern expected for the chemicals in this group.
- Isoxaflutole is the only HPPD inhibitor with a $q_1$* (cancer risk for adults 20-49 years old is 2.8 x $10^{-6}$).
- HED has been reviewing toxicity data for the HPPD inhibitors to determine the appropriate animal model for risk assessment.
    - HPPD inhibitors cause a build-up of tyrosine in the body, and humans and mice have greater capability to utilize an alternate pathway for clearing the excess tyrosine than rats and rabbits. Because rats and rabbits are extremely sensitive, they may not be appropriate animal models for human health risk assessment. HED is therefore excluding toxicity studies conducted with rats and rabbits.
    - Dogs also have a lower capacity for utilizing the alternate pathway for clearing excess tyrosine; however, it was not found to be consistently more sensitive than mice and there was uncertainty as to whether all effects seen in dogs are attributable to the build-up of tyrosine. As a result, in addition to mouse studies, the dog studies will be considered for endpoint selection.
    - A white paper is now being drafted to describe HED's evaluation of mode-of-action and species differences, as well as provide the basis for the HPPD cumulative risk assessment.
- A screening-level cumulative risk assessment is scheduled for completion in Q2 FY21 for mesotrione, isoxaflutole, pyrasulfotole, tembotrione, and topramezone. Other chemicals classified as HPPD inhibitors, such as benzobicyclon, tolpyralate, and bicyclopyrone, are not in registration review but will be included in the cumulative screen.

**Ecological risks:**

- Ecological risks vary across the HPPD Inhibitors, however potential risks are primarily for non-target terrestrial/aquatic plants.

| Pesticide name | Human health risks | Previous ecological risk conclusions |
|---|---|---|
| Mesotrione (PC code 122990) | There are no human health risks of concern expected for chemicals in this group. | Potential risks to terrestrial and aquatic plants (2015 new use assessment). |
| Isoxaflutole (PC code 123000) | | Registration review DRA completed in 2019. Potential risks of concern identified for terrestrial plants only. |
| Pyrasulfotole (PC code 000692) | | Potential risks of concern to terrestrial and aquatic plants and mammals (2010 new use assessment). |

| | | |
|---|---|---|
| Tembotrione (PC code 012801) | | Potential risks of concern to terrestrial/aquatic plants and mammals (2013 SLN assessment). |
| Topramezone (PC code 123009) | | Potential risks of concern to terrestrial/aquatic plants, mammals, and birds (2017 new use assessment). |

**Next Steps:**

- Draft cumulative risk assessment scheduled for Q2 FY21
- PIDs are scheduled for Q3 FY21
- IDs are scheduled for Q1 FY22

**Communications:**

- No significant opposition from stakeholders is anticipated.
- No communications are planned beyond posting in the FR and the public comment period.

# OP DRAs - Phorate & Phosmet (eco only)

Phosmet and phorate are phosphorodithioate organophosphate insecticides that kill via contact and ingestion, acting through inhibition of the acetylcholinesterase (AChE) enzyme.

Phosmet is registered for use on alfalfa, orchard crops (*e.g.,* almonds, walnuts, apples, apricots, nectarines, and cherries), blueberries, citrus, cotton, grapes, ornamental trees and non-bearing fruit trees, Christmas trees, potatoes and vegetable crops to control a variety of insects. Phosmet can also be used to treat fire ant mounds and field margins. Phosmet may be applied in liquid formulations by aircraft and ground spray or through irrigation equipment. Phosmet can also be applied as a dust for postharvest storage of potatoes.

Phorate is used at plant (with soil incorporation) on food crops including beans, sugarbeets, corn, peanuts, potatoes, sorghum, soybeans, and sugarcane, and sweet corn and non-food crops including lilies (field grown), cotton (late in the season), and at bolting for radishes (grown for seed). Phorate targets soil insects like beetles (e.g., rootworms, wireworms) and nematodes. Phorate is available as 10-20% granular end-use products and as 85-95% emulsifiable concentrate manufacturing use products.

**Status of Human Health Risk Assessments**

- The registration review risk assessments will be completed for phorate and updated for phosmet after the SAP meeting this fall. The phorate and phosmet data from comparative cholinesterase assays were originally due in October 2013 and February 2020, respectively, and have not yet been submitted. Based on discussions with the registrant, the CCA data submissions are expected sometime after November 2020 for phosmet and in March 2021 for phorate.

**Phosmet Ecological Risk Assessment Conclusions**

- Phosmet is non-volatile and slightly to moderately mobile. Phosmet hydrolyzes rapidly and is slightly persistent in soil. The residues of concern are phosmet and the phosmet oxon.
- Phosmet is a non-systemic, rapid-acting insecticide/acaricide that is very highly toxic to aquatic vertebrates, aquatic invertebrates, and terrestrial invertebrates and moderately toxic to mammals and birds on an acute exposure basis.
- The DRA identified risk to birds, mammals, reptiles, amphibians, terrestrial invertebrates, fish, and aquatic invertebrates for currently registered use patterns of phosmet.
- A total of eleven incidents are reported in the IDS. Ten involved bees and one was an accidental misuse resulting in a fish kill.

**Phorate Ecological Risk Assessment Conclusions**

- Phorate is moderately mobile and moderately persistent in soil but will degrade rapidly in aquatic systems.
- Phorate is highly toxic to mammals, birds, aquatic and terrestrial invertebrates, and fish on an acute basis. Because of its high toxicity, all phorate end-use products are "restricted use" and are formulated only as granular products to be applied pre- and post-emergent. Phorate is moderately mobile and moderately persistent in soil but will degrade rapidly in aquatic systems.
- Two degradates of concern, phorate sulfoxide and phorate sulfone, are considered along with parent phorate as "total toxic residues of concern" in this assessment. Available data on the degradates suggest similar toxicity to the parent; however, insufficient data are available to

establish definitive fate properties for the degradates, so conservative assumptions are made where necessary.

- At the time of the docket opening, there were 18 reported incidents for birds and mammals, two incidents for plants, and three for aquatic species.

**Communications**

- Significant stakeholder reaction not anticipated at this time.
- No communications are planned beyond posting in the FR and the public comment period.

# Sulfuryl Fluoride Residential Post-Clearance Assessment (and EFED DWA/DRA)

### Current Status

- Structural and commodity fumigant
- Restricted use pesticide (RUP) registered for dwellings, buildings, warehouses, construction materials, furnishings, vehicles, and food commodities (e.g., grains, dried fruit, dried beans)
- Used to control a wide variety of pests, including termites, powder post beetles, old house borers, bedbugs, carpet beetles, clothes moths and cockroaches as well as rats and mice

### Key Points

- Methyl bromide replacement and only fumigant with residential uses.
- After several incidents involving residential fumigations, the 2016 Office of the Inspector General Report recommended that the EPA validate the effectiveness of sulfuryl fluoride clearance devices (e.g., handheld detectors) in detecting the current required clearance level of 1 ppm and implement new device clearance guidance (if needed).
- BEAD completed the clearance device testing and the EPA will publish these results along with the residential post-clearance assessment and the updated incident report to the registration review docket in late September.
- A separate human health risk assessment will be conducted to address occupational, bystander, and ambient exposures for all uses in addition to dietary exposure to sulfuryl fluoride and fluoride from treatment of food commodities. This DRA is scheduled for FY 2021 Q2.

### Human Health Risk Assessment Conclusions (Residential Post-Clearance Only)

- Since the last assessment, an 11-day special inhalation neurotoxicity study in juvenile rats was received and selected for the acute and short-term inhalation endpoints. This study is undergoing re-evaluation and other studies are being considered. Once the endpoints have been re-established, the exposure assessment will be updated accordingly.
- HED analyzed residential post-clearance (5 ppm or 1 ppm) SF air concentration data from three studies to predict potential inhalation exposure after re-entry.
    - In the 3 studies, all fumigated structures were furnished, and were aerated according to California Aeration Plan (CAP).
    - These studies indicate the clearance level used (i.e., 1 or 5 ppm) does not appear to affect the measured post-clearance SF concentrations when aerating following CAP.
    - Estimated exposure concentrations are based on a rolling TWA, calculated using measured values followed by a decline curve generated using first order kinetics.
    - HED will provide an acute and a short-term assessment detailing if additional time to re-entry is needed, once the toxicity endpoints and HECs have been finalized.
- HED also updated the Tier I incident review.
    - 62 Incidents Main IDS, 228 incidents Aggregate IDS, 168 incidents SENSOR-Pesticides
    - 81-91% low severity
    - Several fatalities (most due to breaking/entering a tarped structure during fumigation)
    - Majority (60%) of non-lethal incidents occurred post-clearance, several involved young children

### Ecological Risk Assessment Conclusions

- The drinking water assessment and ecological risk assessment were qualitative and also evaluated inorganic sulfites and metal phosphides & phosphine, other structural and commodity fumigants.

- Due to its high volatility, registered use patterns that are primarily within closed structures or containers, and rapid degradation when released into the atmosphere, sulfuryl fluoride is not expected to be found in surface water or shallow ground water that serve as drinking water sources.
- Additionally, the indoor use patterns limit the potential for environmental exposure, thus, there is a minimal potential for risk to non-target terrestrial and aquatic organisms.

**Communications**

- Before publication, PRD and BEAD will brief the registrant, device manufacturers, and potentially other stakeholders (e.g., California, Florida, NPMA, ASPCRO) on the results of the clearance device testing. Scheduling for second week of September.
- Along with the residential post-clearance assessment, the EPA will publish BEAD's full report of clearance device testing to the SF registration review docket to be transparent to the public (late September).
- FEAD is drafting an OPP Update, an email newsletter to send to stakeholders, announcing the release of the assessment and comment period.

# Zinc Phosphide DRA

**Current Status**

- Moved to Q4 to align with phosphine PID.
- Zinc phosphide is an inorganic compound registered as a rodenticide for agricultural use and non-agricultural use such as golf courses, rangeland, airports, industrial plants, lawns, right of ways, etc.
- Unique among rodenticides in having tolerances
- Can be applied in a variety of methods including aerial broadcast

**Key Points**

- High risk/ high benefit
- The compound is formulated as tracking powder or bait, which when combined with stomach acids produces phosphine gas resulting in death.

**Human Health Risk Assessment Conclusions**

- HED is taking a qualitative dietary assessment approach based on low presence of residues and consistency with the phosphine dietary assessment
- The ORE assessment will be similar to the anticoagulant rodenticides. Exposure is anticipated; however, a qualitative assessment will be conducted. This strategy aligns with the agency's risk management goals to minimize non-target (human) exposure.
- Dermal toxicity data are outstanding but are not required for registration review given that the ORE assessment will be qualitative.

**Ecological Risk Assessment Conclusions**

- The DRA provided multiple lines of evidence indicating risk of mortality to terrestrial vertebrates through direct consumption of bait and secondary poisoning via consumption of contaminated prey.
- There are many incident reports involving wildlife and pets.
    - Birds: Since the RED (1998), there have been 34 incidents reported.
        - These incidents involve mortalities of thousands of geese and hundreds of turkeys.
        - All incidents involve primary exposure.
        - The certainty index is often highly probably due to detections of zinc phosphide or phosphine.
        - The most recent incident was reported in 2019.
    - Mammals: Since the RED, there have been 4 incidents reported, with the most recent incident in 2008.
        - One incident report involves secondary exposure.
    - Aggregate wildlife incident reports: Since the RED, 4 incidents were reported.
    - Pets: There were 505 incidents involving domestic animals.
        - 41 were fatalities.
- Risks are considered low for:
    - Aquatic animals;
    - Aquatic and terrestrial plants; and
    - Terrestrial invertebrates.

**Communications**

- None expected beyond posting in the FR and public comment period. A high volume of comments are expected.

## Ziram DRA

### Current Status

- A dimethyldithiocarbamate fungicide (conventional) and materials preservative (antimicrobial)
- Registered for conventional use on almond, apple, apricot, blackberry, blueberry, cherry, grapes, nectarine, peach, pear, pecan, tomato, christmas tree plantations, conifers, ornamentals
- Registered for antimicrobial use as: materials preservatives for adhesives, wallboard joint compounds, emulsion paints, paper and paperboard, paper coatings, caulks and sealants
- Applications are made by air, ground boom, air blast sprayer, and high-pressure hand wand Applications of ziram include dormant and foliar treatments.
- Thiram is the common metabolite of both ziram and ferbam. DRAs for thiram, ferbam, and ziram are all due at the same time.

### Key Points

- The biggest agricultural use is on almonds, peaches and apples; 50% to 80% of treated acreage of almonds, peaches, and apples is treated at maximum label application rate
- The ziram risk assessment for the conventional uses relies heavily on thiram/ferbam risk assessments which are all due at the same time.
- An antimicrobial end use product results in food and residential uses that are being incorporated into the aggregate risk assessment. The airless spray scenario from the paint use also results in an inhalation risk.

### Human Health Risk Assessment Conclusions

- The DRA includes updated endpoints/PODs and dermal absorption factor (10%).
- For the conventional uses:
    - Dietary Risk: The acute and chronic assessments were refined. There were no risk estimates of concern (all subgroups used <6% aPAD, <2% cPAD).
    - Spray Drift: Risk estimates are of concern for adults and children at the field edge.
    - Occupational Handler: Assessed assuming PPE and, in some cases, with engineering controls.
        - Dermal Exposure: there were many scenarios of concern.
        - Inhalation Exposure: all scenarios were of concern with one exception: aerial applicator for nurseries.
    - Occupational Post-Application
        - Risk estimates were of concern on Day 0, except for hand weeding of tomatoes and blueberries.
        - Risk estimates were of concern on Day 0 and on Day 23 for bird control, hand weeding, orchard maintenance, and propping activities for apple/cherry/pear applications.
        - Use of DFR data did not substantially improve the risk picture.
- An AD manufacturing use product (MUP) was recently found to be an end-use product and will need to be included in the DRA. This may cause delays due to the need to conduct an updated assessment for pulp and paper uses.
- An end use product (a me-too product of the MUP) that was recently registered in AD in June 2020 is included in the DRA.

- The risk assessment for the paint use results is an inhalation risk of concern for residential painters.

**Ecological Risk Assessment Conclusions**

- Eco assessment currently being drafted, but preliminary results show risks to birds, mammals, bees, fish, aquatic invertebrates, and non-vascular plants (terrestrial plants and aquatic vascular plants not at risk). Because ziram rapidly breaks down to thiram (within days) a total toxic residues approach was used which conservatively considered exposure and toxicity considerations of both compounds.
- The eco assessment for the AD uses are still being determined.
- EDWCs for ferbam and thiram are all below the DWLOCs

**Communications**—Registrants and end users likely to provide comments on risk assessment conclusions based on scope and degree of risk, and implications for mitigation. There are 3 registrants for ziram.

# Q4 Conventional DRA Summaries

## Benzyl benzoate Human Health DRA:

Benzyl benzoate is scheduled for both a draft human health risk assessment and a proposed interim decision this quarter, and the summaries for both appear in the under the [ HYPERLINK \l "_Benzyl__benzoate" ] below. The ecological risk assessment for benzyl benzoate was posted in the docket in 2016, with a "no effects" determination for listed species.

## Butoxypolypropylene glycol (BPG):

BPG is scheduled for draft ecological and human health risk assessments and a proposed interim decision this quarter, and the summaries for both appear under the [ HYPERLINK \l "_Butoxypolypropylene_glycol_(BPG)" ] below.

## Difenoconazole:

Release human health and ecological risk assessments. Difenoconazole is a broad-spectrum systemic triazole fungicide that works by inhibiting cell membrane formation. It is registered for use on plants and seeds of various fruits, vegetables, cereals, and field crops. Non-agricultural uses include landscape ornamentals, parks, institutional sites, golf courses and residential properties. The human health risk assessment is currently under development. Updates to the hazard profile include removal of dermal endpoints and upward revisions to all other endpoints except for the acute dietary endpoint. Dietary, residential, aggregate, and occupational risks are not anticipated to be of concern. For the ecological risk assessment, which is currently under review, there are potential chronic risks of concern to birds, mammals, fish, and invertebrates. Environmental fate data suggest difenoconazole is persistent in the environment and may accumulate over repeated applications. Difenoconazole has the potential to bioaccumulate in the aquatic food web, resulting in chronic LOC exceedances for piscivorus birds and mammals. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

## Fenbuconazole:

Release human health and ecological risk assessments. Fenbuconazole is a broad-spectrum systemic fungicide of the triazole (conazole) chemical class. It is currently registered for use on almonds, apples, bananas, blueberries, citrus fruits, cranberries, pecans, peanuts, peppers, stone fruits, sugar beets and wheat. There are no registered residential uses. Fenbuconazole is classified as a Group C, or possible human carcinogen, therefore EPA is evaluating potential cancer and non-cancer human health risks of concern. The toxicological and residue chemistry databases are complete. The DRA will include updated toxicity endpoints/PODs. No human health risk estimates of concern are anticipated. The fenbuconazole eco assessment is still in-preparation but it is anticipated that there are risks to the following taxa; chronic risk to mammals, acute risks to larval bees, acute and chronic risk to freshwater and estuarine/marine fish, chronic risk to freshwater (water-column) invertebrates, risk to estuarine/marine sediment-dwelling invertebrates; and potential risks to mammalian species via consumption from aquatic organisms. Anticipated stakeholder feedback: Minimal stakeholder feedback is anticipated.

**Ferbam:**

Release human health risk assessment. Ferbam is a dimethyldithiocarbamate fungicide on grapefruits and oranges in Florida to control scab disease. It is also used to control anthracnose disease on mangoes in Florida (as a special local need registration). Other agricultural use sites for ferbam include apples, citrus, cranberries, pears, peaches, and nectarines. There are no non-agricultural use sites and no residential uses for ferbam. Ferbam rapidly degrades to the more persistent thiram, so no DCI was issued for ferbam. All the data needed is called in on thiram. Human health assessment currently being drafted, but preliminary results show no acute or chronic dietary (food and drinking water) risks of concern for ferbam. Acute and chronic aggregate risk estimates include food and drinking water only and are not of concern. Most occupational handler scenarios result in dermal and/or inhalation risk estimates of concern even with additional PPE or engineering controls. Most occupational post-application scenarios result in dermal risk estimates of concern at the current label REI of 24 hours (one day after treatment). Some scenarios are still of concern at 30 days, or longer, after treatment. Indirect exposures to ferbam as a result of spray drift are not of concern. The ecological risk assessment is currently being drafted, but preliminary results show potential risks to: birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk). Because ferbam rapidly breaks down to thiram (within minutes to hours), a total toxic residues approach was used which conservatively considered exposure and toxicity considerations of both compounds. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

**Thiram:**

Release human health risk assessment. Thiram is a dimethyldithiocarbamate fungicide registered for use on the following: apples, strawberries, peaches; non-bearing trees, shrubs, nursery stock, and ornamentals as an animal repellent to protect crops from damage by rabbits, rodents, and deer; golf course turf tees and greens; and as a seed treatment (non-food). The human health risk assessment is currently being drafted. The ecological risk assessment is also currently being drafted, but preliminary results show potential risks to birds, mammals, bees, fish, and aquatic invertebrates (terrestrial plants and aquatic plants not at risk, with the exception of direct water application for the cranberry use). Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

**Tolfenpyrad:**

Release human health and ecological risk assessments. Tolfenpyrad is a broad-spectrum pyrazole insecticide and fungicide registered for agricultural uses. Products containing tolfenpyrad are registered for use on a variety of crops, on greenhouse and outdoor ornamental plants, and to control horn flies and face flies on beef and dairy cattle. The human health hazard assessment for tolfenpyrad is being updated, and the dietary, residential, and occupational exposure and risk assessments are in development. Based on previous assessments and preliminary exposure modeling, potential ecological risks are anticipated for all taxa except for terrestrial and aquatic vascular plants. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

# Q4 Antimicrobial DRA Fact Sheets

## Ethylene Oxide (EtO) DRA

**Current Status**

- EtO is a fumigant used to sterilize medical devices and spices.
- The sterilization process is conducted in enclosed chambers.
- There are no residential uses of EtO.
- The OPP science divisions have begun the initial drafting of a semi-qualitative risk assessment for ecological, non-occupational/bystander, and occupational exposures. Dietary exposures to ethylene chlorohydrin, ECH (an EtO reaction product), will be evaluated quantitatively for the spice use.
- Publication Target: OPP aims to coordinate closely with OAR, whose sterilizer assessment is poised for completion in August 2020. OAR plans to complete their first draft of summarizing the worker air concentration data at the end of July and share that data with OPP. The previous target completion scheduled of September 2020 for OPP's EtO DRA will likely be impacted by the coordination with OAR to obtain air monitoring data. Additionally, peer review of the DRA by OAR and ORD will be needed prior to release for public comment. Therefore, we request the new target completion date to be December 2020.

**Key Points**

- EtO is considered a high risk and high benefit chemical.
- The EtO Reregistration Eligibility Decision (RED) was issued in March 2008 by OPP.
- The cancer risk via inhalation for EtO identified in the 2016 IRIS assessment has gained national attention, particularly following the release of OAR's NATA tool in 2018 which showed increased risk in specific communities.
- EtO is the only sterilization method available for many medical devices, having no alternatives in many cases.
- Approximately 50% of all medical devices and 32% of whole spices (including herbs) are treated with EtO in the U.S. annually.
- EtO facilities that had been shut down or voluntarily closed in Illinois and Georgia due to concerns over emissions have recently received orders to re-open to assist in sterilizing medical equipment in response to COVID-19.
- Due to the high visibility of this case, an Ethylene Oxide Interagency Task Force has been formed between EPA (OPP, OAR, and ORD), FDA, CDC-ATSDR, and OSHA. Meetings occur on a monthly basis.
- Ethylene Oxide Task Force (EOTF) has proposed mitigation for label changes that the Agency plans to consider once we move into the decision stage of this case. It includes emission controls, PPE for specific job duties, and deletion of minor uses (artifacts, library materials, cosmetics).
- FDA had provided a benefits statement to OPP on February 7, 2020. EOTF submitted a benefits statement on May 6, 2020. These documents will be considered for the benefits analysis.
- Texas Commission on Environmental Quality (TCEQ) finalized their [ HYPERLINK "https://insideepa.com/sites/insideepa.com/files/documents/2020/may/epa2020_0855.pdf" \t "_blank" ] on May 15th.
- ATSDR is drafting an EtO Toxicity Profile, which is a summary of the information available from IRIS. They did not develop their own inhalation unit risk (IUR) value, and this report does not contain a cancer assessment. OPP reviewed and provided comments for ATSDR's Tox Profile in March 2020.

- OPP seeks approval to delay the September 2020 deadline for the DRA to December 2020 because the OAR assessment has not yet been finalized. OAR anticipates publication by the end of summer 2020; however, this is subject to change. Further, the OPP scientists require more time to review the Exponent White Paper, after having attended a two-part presentation on the information contained in the White Paper on June 16 and June 18. We suggest ensuring the OAR assessment is final before finalizing the OPP assessment, as these will be integral sources of information. As of July 22, OPP has not received all the necessary information from OAR. Further, HED will not be able to complete the spice use assessment until September 1, due to additional unexpected analyses required. Coupled with the extensive review process involving AD, PRD, HED, OAR, ORD, and OGC, we are requesting to delay the DRA to Q1 of FY21.

**Human Health Risk Assessment Conclusions**

- The inhalation exposures to EtO will be addressed semi-qualitatively by providing abbreviated evaluations of the hazard assessments (how EtO was assessed, key differences in modeling approaches, peer review process, results) published by IRIS, EtO's industry Task Force (Exponent), EPA's 2008 RED, and Texas Commission on Environmental Quality. The EtO air monitoring data available from OAR to be included in the assessment will include ambient monitoring results from 17 sites (locations with no known EtO sources, national average ~0.297 ppb) and non-occupational/bystanders (not obtained yet). Worker's air monitoring data from within contract sterilization facilities, including some spice treatments, are available from both OAR and registrant submissions.
- EPA will present all the various sources of toxicity information for EtO in a science narrative. The strengths and weaknesses of all data sources will be discussed as part of the WOE analysis. Inhalation cancer risks for EtO are the risk driver. Inhalation cancer risks are likely triggered irrespective of the various sources of toxicity data.
- OPP's assessment will not choose one cancer endpoint over another. Instead, the range of values from IRIS to TCEQ/Exponent will be presented in a qualitative science narrative (there is a 3-fold range in the inhalation unit risk (IUR) values for EtO).
- Preliminary worker's air monitoring data submitted by the registrant indicates average EtO air concentrations from 25 sterilizer facilities at 0.23 ppm (when accounting for respirators worn) and 0.12 ppm at 34 health care facilities (no respiratory protection). Minimal information on actual facilities are available.
- Risks of concern for workers and bystanders will be based on a semi-qualitative approach, with an emphasis on an expedited path toward mitigation.
- A quantitative chronic dietary assessment is underway for the dietary residue of concern, ECH.
- Chronic dietary endpoint selected for ECH is based on a two-generation reproductive toxicity study showing body weights, thyroid, spleen, kidney, and adrenal gland effects.
- Dietary exposures to ECH (an EtO reaction product) are evaluated quantitatively for the spice use. The unrefined chronic dietary assessment for ECH shows no risk concerns for any population subgroup. The assessment is being updated from the 2006 RED.

**Ecological Risk Assessment Conclusions**

- Limited risk to the environment from registered uses.

**Communications**

- Due to the sensitive nature of this case, we anticipate extensive public comment from community groups, industry, American Chemistry Council, states, politicians, federal agencies, NGO's, and individual community members.

- OPP monthly calls internally with OAR and ORD and externally through the Interagency Task Force.
- There is an Agency-wide risk communication group for EtO that includes members from OAR and FEAD, which is developing an informational tool kit. There will be four documents ready for review in August, with information on risks, EPA's role in regulation, and EPA's actions. OPP's representative is Quinn Pennington.

# Q4 Antimicrobial DRA Summaries

## Benzoic Acid:

Release human health and ecological risk assessments. Benzoic acid is a bactericide and is formulated for use as a preservative of food-grade lubricating oils in industrial facilities and in textiles, polymers, and plastics. Human dietary exposure to residues of benzoic acid from pesticidal sources is expected to be minimal compared to the direct food-additive uses regulated by FDA. Therefore, a qualitative dietary assessment has been performed. Occupational dermal risk is not expected for the registered use of benzoic acid. The inhalation risk to benzoic acid will be determined after the available inhalation study is taken to HED's ToxSAC for review in early August 2020. The risk to terrestrial and aquatic organisms (including plants) is expected to be negligible. At this time, the Agency concluded that based on low hazard and exposure, the registered uses of benzoic acid will have a "no effects" determination under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species. Anticipated stakeholder reaction: minimal stakeholder feedback is anticipated.

## Dimethoxane:

Release human health and ecological risk assessments. Dimethoxane is a bacteriostat and fungistat. It is registered as a materials preservative for use in industrial adhesives, paints, coatings, emulsions, slurries, inks, textile chemicals, leather processing, and distillation fuels. There are no oral exposures from uses of dimethoxane products. There are no residential handler risks of concern for dimethoxane. There are no occupational dermal or inhalation risk of concerns for dimethoxane. Dimethoxane and its degradates are not expected to result in risk to terrestrial or aquatic species (including pollinators). Based on the low exposure potential from antimicrobial uses of dimethoxane as well as low toxicity to non-target terrestrial and aquatic organisms, the Agency has made a "no effects" determination for dimethoxane under the Endangered Species Act (ESA) for all listed species and designated critical habitats for such species. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

## Polymeric Betaine:

Release human health and ecological risk assessments. Polymeric betaine is a wood preservative, borate ester, that breaks down to DDAC and boric acid when applied to wood. It is registered as a microbiocide, fungicide, and insecticide applied through pressure treatment. Dietary exposure to polymeric betaine via food is not expected because the labels prohibit use on wood that may come into contact with food or feed. Residential post-application dermal and incidental oral exposures to polymeric betaine are of concern. Occupational dermal and inhalation exposures for composite wood workers and pressure treatment are not of concern. Occupational inhalation exposure for sapstain control worker are also not of concern. Occupational dermal exposure for sapstain control worker are of concern. There are no ecological risks of concern from the wood preservation use from polymeric betaine, DDAC, or boric acid from the registered uses of polymeric betaine. The assessment is still being conducted, but the Agency will likely be able to make a 'no effects' call for listed species and their designated critical habitats for the current uses of polymeric betaine. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

## Q4 BPPD DRA Fact Sheets

None

## Q4 BPPD DRA Summaries

None

# Q4 Proposed Interim Decisions

## Q4 Conventional PID Fact Sheets

Note: The commodity fumigants are scheduled for combined draft risk assessments/proposed interim decisions this quarter, and the summaries for both appear in this section.

### Commodity Fumigant DRAs and PIDs – Aluminum Phosphide, Magnesium Phosphide, Phosphine, Propylene Oxide (PPO) & Inorganic Sulfites

**Current Status**

- Aluminum (Al) phosphide was first registered for use in the US in 1958, followed by magnesium (Mg) phosphide in 1979, and phosphine, formulated as a gas, in 2002. Al phosphide and Mg phosphide are registered for use outdoors in burrows for rodent control. All three active ingredients are also registered for indoor use on numerous food (post-harvest) and nonfood items as an insecticide and rodenticide.
- PPO was first registered in 1982 and is an insecticidal commodity fumigant and sterilant used to prevent bacteria, mold contamination, and microbial spoilage as well as insect infestations on food and nonfood products. PPO is registered for use on numerous food (post-harvest) and nonfood items, including cosmetics, packaging, non-edible gums, ores, and pharmaceutical materials.
- Sulfur dioxide ($SO_2$) was first registered for use in the US in 1988, followed by sodium metabisulfite in 1989. As active ingredients, these chemicals are fungicides typically used to treat *Botrytis cinerea*, the fungus which causes bunch rot, or gray mold disease on grapes. These products are used in cold-storage warehouses, trucks, vans and train cars for post-harvest grape fumigation. In addition to the fungicidal use against *B. cinerea*, sulfur dioxide is also used in combination with carbon dioxide to treat for black widow spider on grapes in warehouse settings. The black widow spider treatment is not included on any sulfur dioxide product labels, as this use is permitted solely under a FIFRA 24(c) carbon dioxide registration (CA920007). The sodium metabisulfite products are composed of the anhydrous, solid active ingredient contained in semi-sealed pads which are added to containers holding grapes prior to shipping. There is also one antimicrobial product in which sodium metabisulfite is embedded into packaging stickers for use in shipping consumer goods such as footwear, clothing, accessories, and similar materials.
- The risk assessment and risk management strategy was briefed up to the AA in April 2019
- Publication Target (flexible): October 2020
    - The antimicrobial draft risk assessment for sodium metabisulfite will be loaded with the proposed interim decision. There are no risks associated with the antimicrobial use, and, therefore, stakeholder responses are expected to be minimal.
    - The inorganic sulfites conventional-use DRAs were published for a 60-day comments period on May 4, 2020.

**Key Points**

- The commodity fumigants are high risk/ high benefit active ingredients with critical applications in agriculture, trade and other industries. There are often no alternatives to these active ingredients for their registered uses.
- Significant data requirements of the commodity fumigant DCIs were not addressed by the registrants. As a result, OPP was not able to conduct quantitative human health risk assessments for occupational

handler scenarios. Qualitative assessments of worker exposure were instead conducted. Monitoring data to assess bystander exposure to ambient air concentrations of PPO and phosphine were also not submitted. In lieu of these data, the agency used statistical models to assess bystander ambient air exposure. These models are not appropriate substitutes for monitoring data and so potential bystander ambient exposure to PPO and phosphine may not be fully understood.

**DRA Human Health Conclusions**

- Commodity fumigants are highly volatile, and the majority of the fumigant is expected to off-gas quickly from treated commodities and materials; therefore, significant dietary exposure is not expected.
  - PPO: No toxic effects relevant to humans were identified from consumption of PPO residues, while dietary assessment of reaction product PCH does not show risks of concern.
  - SO2: No (food only) dietary risks of concern (when sulfite residues < FDA standard of 10 ppm)
- Occupational handlers: Qualitatively assessed
- Occupational post-application: Qualitatively assessed.
- Residential handlers and post-application: Products are all Restricted Use (RUP) and not applied to residential areas so no assessment was conducted.
- Bystander (drift and/or volatilization): Quantitative buffer assessments using the PERFUM model were conducted. PERFUM recommended buffers ranging from 0 m to 2,500 m, based on the fumigant in question and various assumptions about the treatment facility.
- Bystander ambient air: Monitoring data not available; exposure assessed using modeling.
  - SO2 regulated by EPA's Office of Air Quality Planning and Standards (OAQPS)

**DRA Ecological Conclusions**

- Limited risk to the environment is expected from registered uses of these active ingredients. The commodity fumigants are volatile and expected to disperse quickly in the environment, mitigating exposure.
- PPO only: The risk assessment identified potential risks of concern to terrestrial mammals in close proximity to a treated site. The modeling scenario that yielded risks of concern assumed an aeration stack height of five feet with one air exchange per hour and a strong, downward draft of wind from the top of the stack. Other stack configurations and wind conditions may not pose a risk to mammals.
- There have been six ecological incidents reported with Al phosphide and one incident with phosphine (involving wild turkey mortalities), as of 2019. One aggregate incident involving plant damage was also reported for Al phosphide. No incidents were reported for Mg phosphide, PPO, sodium metabisulfite or sulfur dioxide.

**Proposed Mitigation in PID**

- Aluminum phosphide, Magnesium Phosphide, Phosphine & Propylene Oxide (PPO): To protect workers and bystanders, EPA is proposing revised/requiring fumigation management plans (FMPs). Based on the results of the buffer assessments, EPA may also propose buffer zones around treatment sites. FMPs describe how and when a fumigant will be applied, include plans to respond to leaks or accidents, specify storage guidelines, and outline other protective measures. A buffer zone is a radius around an application site that personnel may enter only if wearing personnel protective equipment (PPE) during application and aeration times. Buffer zones are calculated on site depending on chamber size, application rate, stack height and configuration, and other factors.
- Sodium Metabisulfite: No mitigation is proposed for the antimicrobial use of sodium metabisulfite as no human health or ecological risks were identified.

**Communications** – No rollout is proposed beyond the normal public notice and comment period.

# Q4 Conventional PID Summaries

Note: Benzyl benzoate and butoxypolypropylene glycol are scheduled for combined draft risk assessments/proposed interim decisions this quarter, and the summaries for both appear in this section.

**Benzyl benzoate (benylate) Human Health DRA and PID:**

Release draft human health risk assessment and Proposed Interim Decision. Benzyl benzoate is an insecticide/miticide with only one registered conventional pesticide product, a spray for treatment for sarcoptic mange mite on dogs. No dietary exposures are expected. The agency is currently evaluating the potential inhalation risk. For ecological effects, at the time of the Problem Formulation, the agency previously concluded that benzyl benzoate is not expected to pose risks of concern, and also made a "no effects" determination for listed species. These conclusions are based on the limited potential for environmental exposure, limited extent and diffuse nature of use, and the low toxicity of benzyl benzoate as demonstrated by available toxicity test data and corroborated by structural activity information. No mitigation is proposed for benzyl benzoate due to the absence of risks of concern from the use of this chemical. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.

**Butoxypolypropylene glycol (BPG) Ecological DRA and PID:**

Release draft risk assessments and Proposed Interim Decision. BPG is used to repel flies, mosquitoes, fleas, and ticks in areas where animals live and for direct application to companion and equine animals. There are no food uses, no uses on animals intended for slaughter, and outdoor misting systems are prohibited. There are no dietary, residential, aggregate, spray drift, or occupational risks of concern. No potential ecological risks of concern are anticipated. Some label clarification will be proposed. Anticipated stakeholder reaction: Minimal stakeholder feedback is anticipated.